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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/050,249	03/30/1998	HARUKI OKAMURA	OKAMURA=2B	6601

1444 7590 07/26/2006

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EXAMINER	
JIANG, DONG	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/050,249	OKAMURA ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *93,95 and 98-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *93, 95 and 98-120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's amendment filed on 08 May 2006 is acknowledged and entered. Following the amendment, claims 96 and 97 are canceled, claims 93, 98-101, 104, 109 and 120 are amended.

Currently, claims 93, 95 and 98-120 are pending and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 96 and 97 are moot as the applicant has canceled the claims.

The rejection of claims 93, 95, 98-117 and 119 under 35 U.S.C. 112, first paragraph, for lack of adequate written description is withdrawn in view of applicant's amendment.

The scope of enablement rejection of claims 93, 95, 98-117 and 119 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's amendment.

Rejections under 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 118 remains rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description for the reasons set forth in the previous Office Actions.

Claim 118 also remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a monoclonal antibody specifically recognizing a polypeptide of SEQ ID NO:2, wherein Xaa is Met or Thr, does not reasonably provide enablement for claims to a monoclonal antibodies to any or all "interferon-γ inducing protein". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in

scope with the claim, for the reasons of record set forth in the last Office Action (page 4) mailed on 12/16/05.

There is no argument toward above rejections in the applicants response.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 93, 95 and 98-120 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura *et al.* (*Infect. Immun.* 61: 64-70, 1993), for the reasons set forth in the previous Office Actions.

Applicants argument filed on 08 May 2006 has been fully considered, but is not deemed persuasive for reasons below.

At pages 10-15 of the response, the applicant argue once again that Nakamura's "factor" is different from that of the instant invention. Applicants repeated previous argument on pages 10-13, that, as previously pointed out by applicants, there are various differences between the polypeptide and the "factor" disclosed in Nakamura's publication, such as the origin of the isolation, MW, activity after SDS-PAGE, and IFN-γ inducing ability (see summary in the table on page 10). This argument is not persuasive for the reasons of record.

Applicants further argue, on pages 13-14, that it is unreasonable to hold that the Nakamura's "factor" is the same as that of the later publication even if the later "factor" is contained in the former, and that Dr. Okamura's declaration filed on 9/28/05 states "we speculated that the factor could possibly be natural killer stimulatory factor (NKSF) IL-12", which also has IFN-γ inducibility, and thus, Dr. Okamura (one of the authors of the Nakamura reference) did not even consider the "factor" to be the polypeptide with a MW of 19,000+5,000. This argument is not persuasive for the reasons of record, specifically, as addressed in the previous Office Actions, the post filing date reference by Okamura (not Nakamura, *Infect. Immun.* 63: 3966-3972, 1995, it was first cited in the Office Action mailed on 2/11/02. Note, it was previously once mis-cited as "Nakamura" reference, Office Action mailed on 2/11/04, page 5), from the same group of investigators, confirms that IGIF in the serum sample (the 75 kDa, Nakamura, *Infect. Immun.* 61: 64-70, 1993) was proved to be the same IGIF as that found in the liver extract (19 kDa), and it was considered to be bound to another protein or to exist in an oligomeric form (page 3969, the second paragraph of the left column). Therefore, it is irrelevant as to how or what Dr. Okamura *considered* the "factor" might or might not be originally, as *the fact is* that Nakamura's "factor" is the same as that of the present invention as disclosed in the later Okamura reference. Furthermore, as admitted by applicants, "the later 'factor' is contained in the former", therefore, since the antibody to Nakamura's "factor" is obvious (as addressed previously), it would inherently make the present antibody obvious because the antibody to Nakamura's "factor" would inevitably comprise the antibody to the polypeptide in the present invention.

Applicants further argue, on page 14, that there is a difference in specific activities between Nakamura's "factor" and Okamura's "factor" as Nakamura's "factor" has the specific activity of 283,333 U/mg after purification with Phenyl-Sepharose (Table 1 of the Nakamura reference), whereas Okamura's "factor" has the specific activity of 14 U/mg after the same purification (Table 1 of the Okamura reference); and that the specific activities of the both factors should be the same after the same purification procedures. This argument is not persuasive because of the following: first, the specific activity is the same between the two with respect to the biological activity, i.e., inducing IFN-γ, and they are only "different" in degree or

intensity of the activity. Second, the sources of isolation and the purification procedures between the two references are different. As shown in Table 1 (page 66) of the Nakamura reference, the "factor" was isolated from sera, and there are three major steps (ammonium sulfate, DEAE-Sepharose, and Ultrogel) involved before the step of Phenyl-Sepharose. In contrast, Okamura's "factor" was isolated from liver, and the Phenyl-Sepharose step follows right after ammonium sulfate step, i.e., the two steps of DEAE-Sepharose, and Ultrogel are missing before Phenyl-Sepharose as compared to Nakamura's procedure. As such, it would be expected that Nakamura's "factor" has higher specific activity because of the additional purification steps. Finally, *even if* the purification procedures were the same, it is well known that different experiments may result in difference in purity and/or biological activity of an isolated protein, and therefore, no conclusion can be drawn regarding the distinct identity of the protein molecules based simply on comparing the unit activity of an isolated protein purified from different experiments.

Conclusion:

No claim is allowable.

Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
7/12/06

GARY B. NICKOL, PH.D.
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